DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

REPLY TO
ATTENTION OF

12 MAR 2003

DASG-PPM-NC

MEMORANDUM FOR Commanders, MEDCOM Major Subordinate Commands

SUBJECT: Army Policy on the Use of Non-US Food and Drug Administration (FDA) Licensed Blood and Blood Products

1. References:

a. Memorandum from ASD-HA, Subject: "Policy on the Use of Non-US Food and Drug Administration (FDA) Licensed Blood Products," 4 December 2001 (enclosed).
b. Joint Pub 402.1, Joint Tactics, Techniques and Procedures for Health Service Logistics Support in Operations, 6 October 1997, Chapter IV, Blood Management; paragraph 10, Host- Nation Support.
c. Field Manual 8-70, Standards for Blood Banks and Transfusions Services
d. Army Regulation 40-400, Patient Administration, 12 March 2001, Chapter 10.

2. Reference 1.a. provides guidance on the use of unlicensed blood products in DoD medical treatment facilities (MTFs) overseas. It further requires that each Service develop and implement a process to identify, document, and track Active Duty and other DoD beneficiaries who receive these transfusions at overseas MTFs or at Host Nation (HN) medical facilities..

3. This memorandum augments HA Policy 01-020, providing additional guidance to AMEDD personnel regarding counseling, the scope of responsibilities of the treating physician, and the prescribed follow-up protocol for patients receiving this kind of transfusion.

4. Procedures.

a. Identify.

1) In overseas US military MTFs , the treating physician will verify and document the required, emergent need for the use of untested or non-FDA licensed blood and/ or blood products. Standard forms documenting informed consent should specify that the use of non-FDA licensed blood products was medically required and explained to the patient, in advance, if possible.

2) For transfusions done in HN facilities, the treating US military physician will document the details of the transfusion event in the patient's record, obtain as much information as possible from the HN treating facility about the nature of and any testing done on the blood product, assure that the patient has been informed, and begin baseline documentation and tracking as outlined below.

3) When an Active Duty soldier or other DoD beneficiary receives a non-US FDA licensed transfusion of blood or blood products at a HN hospital, the US military physician who becomes the patient's treating physician is responsible for identification, documentation, and initial testing of that patient.

4) The treating physician will ensure that the patient has been informed and counseled about the use of non-US FDA licensed blood and blood products and will explain in detail the need for post-transfusion testing, including the types of tests and the testing schedule.

5) Active Duty soldiers and other DoD beneficiaries should be questioned about any emergent medical care received in a HN medical facility and asked specifically whether they received any blood or blood products.

6) If during the post deployment health assessment, a service member answers 'yes' to questions about medical occurrences during deployment, the member should be further questioned about possible non-FDA licensed blood transfusion so that appropriate documentation, counseling, and follow-up testing is done.

b. Document.

1) The treating physician must make a progress note in the medical record detailing pre-transfusion informed consent (when applicable), post-transfusion notification, and counseling. A separate progress note is required even if the patient has signed a preprinted consent form.

2) Documentation of initial baseline and follow-up testing for transfusion-transmitted infectious agents must be recorded on a DD Form 2766, Mar 1998, page 2 of 4, Section 7, Screening Exams.

3) An entry noting "Non-FDA licensed blood product transfusion recipient" must be made on DD Form 2766 when entering the results of any the required screening exams listed below under "Tracking".

c. Track.

1) The treating physician must report all non-FDA licensed blood and blood product transfusions of DoD beneficiaries within 30 days to the Army Blood Program Office (ABPO) Quality Assurance Manager, U.S. Army Medical Command, Fort Sam Houston, Texas by electronic copy Kathleen.Elder@amedd.army.mil or by telephone (210) 221-6344/7989. Reports must include the patient name, social security number, date of birth, date/ type/ and number of blood product(s) transfused, and origin of blood. The Army Blood Program Office will maintain the transmitted patient information and forward a report to the Armed Services Blood Program Office within one week of receipt of the original report.

2) Recipient Follow-up Testing. In accordance with HA Policy 01-0202, each patient transfused with non-US FDA licensed blood products must be tested in the following manner:

a) A blood specimen should be obtained from the recipient prior to transfusion, if possible, to determine base-line serological studies for: Hepatitis B, Hepatitis C, HIV, HTLV, Syphilis and other transfusion-related diseases. If a pre-transfusion specimen is not available, a blood sample should be collected as soon as possible after transfusion.

b) Patients will be retested at 3, 6, and 12 months post transfusion for the same serological studies.

5. The points of contact for this policy are COL Regina Curtis, Proponency Office for Preventive Medicine, Office of The Surgeon General, DSN 761-3017, Commercial (703) 681-3017, or e-mail Regina.Curtis@otsg.amedd.army.mil, and COL Gary Norris, Army Blood Program Office, Office of the Surgeon General, DSN 761-0360, Commercial (703) 6810360, or e-mail Gary.Norris@otsg.amedd.army.mil.

Encl

JAMES B. PEAKE, M.D.
Lieutenant General
The Surgeon General

CF (w/encl):
Commander, 18th MEDCOM, ATTN: Surgeon
Director, National Guard Bureau, ATTN: Surgeon, 111 South George Mason, Arlington, VA 22204-1382
Chief, U.S. Army Reserve Command, ATTN: Surgeon, 1401 Deshler Street South West, Fort McPherson, GA 30330-2000
Commander, U.S. Army Training and Doctrine Command, ATTN: Surgeon, 7 Fenwick Road, Fort Monroe, VA 23651-5000
Commander, U.S. Army Forces Command, ATTN: Surgeon, 1777 Hardee Avenue, SW, Fort McPherson, GA 30330-6000
Commander, U.S. Army Materiel Command, ATTN: Surgeon, 5001 Eisenhower Avenue, Alexandria, VA 22333-0001
Commander, U.S. Army Test and Evaluation Command, Park Center IV, 4501 Ford Avenue, Alexandria, VA 22301-1458
Commander, U.S. Army Special Operations Command, ATTN: Surgeon, Fort Bragg, NC 28307-5200

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

RECEIVED
DEC 07 2001

DEC 4 2001

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Policy on the Use of Non-US Food and Drug Administration Licensed Blood Products

DoD policy provides that the standard of care for those beneficiaries who receive a blood transfusion overseas in a DoD medical treatment facility (MTF) shall be equal to that received in a MTF within the United States. Inspection and regulatory requirements over blood and blood products vary widely by country, and even within certain countries, and may not provide for the same level or type of testing as the US Food and Drug Administration (FDA) requires.

This policy memorandum provides guidance on the use of non-FDA licensed blood products overseas in emergencies. It also provides guidance on post-transfusion patient follow-up. The Assistant Secretary of Defense (Health Affairs) "Policy on the Use of Non-DoD, Non-US Food and Drug Administration Licensed Blood Products", dated 12 May 1994, is hereby rescinded. The following policy shall apply to all Department of Defense (DoD) medical facilities. Unified or Specified Commands, and Task Force Surgeons, will report the transfusion of another nation's non-US FDA licensed blood products to the Armed Services Blood Program Office (ASBPO) and the appropriate Service Blood Program Office through the Joint Blood Program Officer.

Blood products received for use in DoD medical treatment facilities (MTFs) from a non-FDA licensed Host Nation or other nations' facilities may be used for the emergent treatment of DoD beneficiaries. Under such circumstances the attending physician must verify and document that the use of untested blood products (by FDA standards) was required for patient care. Each patient transfused with such blood must be tested in the following manner:

- The patients shall have, whenever possible, pre-transfusion blood specimens collected and submitted for testing to determine base-line serological studies for Hepatitis B and C, Human Immunodeficiency Virus, Human T-Cell Lymphotrophic Virus, Syphilis, and other transfusion transmitted diseases as appropriate;
- These patients must be retested at 3 months, 6 months, and 1-year post transfusion;
- If a pre-transfusion specimen cannot be obtained, a blood sample for serological testing shall be collected as soon as possible post transfusion;
- All testing must be completed and documented in the patient's record as soon as practical;

- The Services' Medical Departments are responsible for developing and implementing a process to identify, document, and track post-transfusion testing and care of these patients; and
- Reporting should include national origin of blood, type and number of blood product(s) transfused, and patient name and identification number.

In addition to the testing requirements, the patient shall be given notice, prior to transfusion if feasible or as soon thereafter as possible, that the blood is not FDA licensed, the reasons it is being provided, and the necessary patient follow-up.

A comprehensive audit of non-FDA licensed facilities, that are used as a source of emergency blood or blood products, may be requested by a Unified or Specified Command, or a Task Force Surgeon. These audits will be made available by the Armed Services Blood Program Office (ASBPO) to the Task Force Surgeon or the Unified Command Surgeon for evaluating the safety of local blood supplies. The purpose of these audits is to understand the extent of donor screening and testing as it compares to US standards. The Armed Services Blood Program Office will publish audit procedures in the form of a blood program letter.

These guidelines shall be implemented within 45 days. Please provide implementation documents to the Director, Armed Services Blood Program Office, 5109 Leesburg Pike, Falls Church, VA 22041-3258. For questions regarding this policy please contact Colonel G. Michael Fitzpatrick, Medical Service, United States Army, Director, Armed Services Blood Program at DSN 761-8024, (703) 681-8024, at glen.fitzpatrick@otsg.amedd.army.mil.

William Winkenwerder, Jr., MD

cc:
Surgeon General, U.S. Army
Surgeon General, U.S. Navy
Surgeon General, U.S. Air Force
Deputy Director for Medical Readiness, J-4